

Economic Impact Statement

LSA Document #08-61

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses**Description of Rule**

The Indiana State Department of Health (ISDH) has responsibility for the licensure of hospitals, ambulatory surgery centers, abortion clinics, and birthing centers under [IC 16-21](#). In January 2005, Governor Daniels issued Executive Order 05-10 requiring the ISDH to develop and implement a medical errors reporting system (MERS). In response to the executive order, the Hospital Council recommended and the ISDH executive board adopted rules requiring the reporting of medical errors resulting in death or serious disability. The rule is based on the National Quality Forum's 27 serious reportable events or 'never' events as they are frequently called. The proposed rule requires hospitals, ambulatory surgical centers, abortion clinics, and birthing centers to have a serious adverse event reporting system in place and requires reports of serious adverse events to be submitted to the ISDH not later than 15 days after the serious adverse event occurs. Data submission occurs online in real time utilizing the existing ISDH electronic portal.

The proposed rule is an update that includes the 28th reportable event adopted by the National Quality Forum in 2007. This change requires the reporting of artificial insemination with the wrong donor sperm or wrong egg. What constitutes a reportable event when a foreign object is left in a patient after surgery is clarified. Reporting of a medication error is clarified. The terminology of "serious adverse event" is changed to "reportable event". The current reporting timeframe is reduced from six months after the potential reportable event is brought to the entity's quality assessment and improvement program to four months.

Economic Impact on Small Businesses**1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

[IC 4-22-2.1-4](#) defines a small business as any person, firm, corporation, limited liability company, partnership, or association that:

- (1) is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
- (2) is independently owned and operated;
- (3) employs one hundred (100) or fewer full-time employees; and
- (4) has gross annual receipts of five million dollars (\$5,000,000) or less.

Health care facilities licensed under [IC 16-21](#), hospitals, ambulatory surgery centers, abortion clinics, and birthing centers are required under the current and proposed rule to report the prescribed events. The ISDH does not have access to information regarding the gross annual receipts or any other financial information from health care facilities licensed under [IC 16-21](#), except hospitals.

The ISDH licenses 141 hospitals. The North American Industry Classification System classifies these institutions as General Medical and Surgical Hospitals (NAICS 622110). The ISDH reviewed data reported by the licensed hospitals. After review of the most recent data submitted by Indiana hospitals, the ISDH has determined that no Indiana hospitals regulated by the proposed rule meet the definition of a small business. All Indiana hospitals reported gross annual receipts in excess of five million dollars.

The ISDH licenses 135 ambulatory surgery centers. The ISDH does not have data on the gross annual receipts of ambulatory surgery centers. Based on factors such as the number and type of procedures performed at the center, the ISDH estimates that fewer than 25 percent of centers would meet the definition of a small business. The ISDH therefore estimates there to be not more than 34 ambulatory surgery centers that are small businesses. The North American Industry Classification System classifies these institutions as ambulatory surgery centers (NAICS 621493).

The ISDH licenses nine abortion clinics. The ISDH does not have data on the gross annual receipts of the abortion clinics. Clinics employ 100 or fewer full-time employees. They may qualify as small businesses. The North American Industry Classification System classifies these institutions as abortion clinics (NAICS 621410).

The ISDH licenses three birthing centers. The ISDH does not have data on the gross annual receipts of the birthing centers. Centers employ 100 or fewer full-time employees. They may qualify as small businesses. The North American Industry Classification System classifies these institutions as midwives' offices or centers (NAICS 621399).

In summary, the number of small businesses impacted by this rule is likely less than 46.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

Any of the facilities that are small businesses already have to comply with the rule. The proposed rule does not add additional costs for annual reporting, recordkeeping, or other administrative costs.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

The total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule is zero.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

[IC 16-21](#) requires the ISDH to license and regulate hospitals, ambulatory surgery centers, abortion clinics, and birthing centers. The statute requires the ISDH to adopt rules to ensure quality assurance standards at the regulated facilities. Additionally, rules and regulations require the facilities to maintain a quality assurance program. The ISDH believes the proposed rules are within the requirements established in applicable statutes, rules, and Executive Order 05-10.

Patient safety is of significant concerns to all Hoosiers. Medical errors have been identified in studies such as the Institute of Medicines 2000 report entitled "To Err is Human" as a significant problem in ensuring health care quality. The ability to collect data on serious adverse events is an important step towards analyzing information in order to improve health care quality through decreasing medical errors. The reduction of serious adverse events would decrease operating costs for health care facilities.

5. Regulatory Flexibility Analysis

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

In order to ensure the ability to obtain complete data, the reporting requirements are the same for all health care providers. The reporting requirement is very minimal. The facility is only required to report the classification of the serious adverse event and the quarter in which it occurred.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

Because the reporting requirements are minimal, there was no need to establish less stringent schedules or deadlines for small business compliance.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

It is expected that the health care facility's quality assessment and improvement program will meet periodically and review any serious adverse events gathered during the period since their last meeting. The program will therefore be able to consolidate events in an efficient manner.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

There are accreditation and certification organizations that have established performance standards for these health care facilities. The standards imposed by this rule were developed by the National Quality Forum in collaboration with health care providers.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

The health care facilities already have quality assurance programs in place pursuant to other requirements. This proposed rule imposes no new costs.

Conclusion

Assuming there may be less than 47 small businesses, there is no economic impact of the proposed rule on health care facilities that are small businesses.

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